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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/462,625      | 07/28/00    | GEORGIEV             | G 0652.1630001      |

HM22/1002  
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WASHINGTON DC 20005-3934

EXAMINER

RAWLINGS, S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1642

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/462,625

Applicant(s)

GEORGIEV ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Election facsimile sheet*.

**DETAILED ACTION**

1. The amendment filed on July 28, 2000 in Paper No. 6 is acknowledged and has been entered.
2. Claims 1-52 are pending in the application and are currently subject to restriction.

***Election/Restrictions***

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- Group 1. Claims 1-23 drawn to an isolated nucleic acid molecule, a vector comprising said nucleic acid molecule, a host cell comprising said nucleic acid molecule, a method of producing a protein encoded by said nucleic acid molecule, an isolated polypeptide encoded by said nucleic acid molecule.
- Group 2. Claim 24, drawn to a method for producing an antibody.
- Group 3. Claims 25-29, drawn to an antibody.
- Group 4. Claims 30, 33, 35-37, and 41-52, drawn to a method for inhibiting the growth of a mammalian tumor or treating a cancer in an animal, wherein said method comprises administering a composition comprising a polypeptide, and a pharmaceutical composition comprising said polypeptide.
- Group 5. Claims 31, 32, 34, 38-40, 41-45, and 48-52, drawn to a method for inhibiting the growth of a mammalian tumor or treating a cancer in an animal, wherein said method comprises administering a composition comprising a nucleic acid molecule.

4. The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group 1 is a nucleic acid molecule.

The special technical feature of Group 2 is immunizing an animal with a polypeptide.

The special technical feature of Group 3 is an antibody.

The special technical feature of Group 4 is contacting a tumor cell with a polypeptide.

The special technical feature of Group 5 is contacting a tumor cell with a nucleic acid molecule.

Accordingly, Groups 1-5 are not so linked by the same or corresponding special technical feature as to form a single general inventive concept. Furthermore, PCT Rules 13.1 and 13.2 do not provide for an invention directed to more than the first product, more than the first method for making said product, and more than the first method for using said product.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Currently, the following claims, which are drawn to patentably distinct species of invention, are generic: claims 1, 8, 18, 30, 31, 33, 34, 42, 43, 47, and 50.

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Claim 1 is drawn to distinct species of the claimed invention, wherein the nucleic acid molecule of claim 1 has a nucleotide sequence that is at least (a) 70%, (b) 75%, (c) 80%, (d) 85%, (e) 90%, (f) 95%, or (g) 99% identical to the reference sequence (claim 2).

Claim 8 is drawn to distinct species of the claimed invention, wherein the epitope bearing portion is selected from the following group consisting of (a) a polypeptide consisting essentially of amino acid residues from about 20 to about 40 of SEQ ID NO: 2, (b) a polypeptide consisting essentially of amino acid residues from about 55 to about 75 of SEQ ID NO: 2, (c) a polypeptide consisting essentially of amino acid residues from about 90 to about 110 of SEQ ID NO: 2, and (d) a polypeptide consisting essentially of amino acid residues from about 145 to about 160 of SEQ ID NO: 2.

Claim 18 is drawn to distinct species of the claimed invention, wherein the polypeptide of claim 18 has an amino acid sequence that is at least (a) 70%, (b) 75%, (c) 80%, (d) 85%, (e) 90%, (f) 95%, or (g) 99% identical to the reference sequence (claim 20).

Claims 30 and 33 are drawn to distinct species of the claimed invention, wherein the polypeptide of claim 30 or 33 has an amino acid sequence that is at least (a) 70%, (b) 75%, (c) 80%, (d) 85%, (e) 90%, (f) 95%, or (g) 99% identical to the reference sequence (claim 35).

Claim 33 is drawn to distinct species of the claimed invention, wherein the cancer is (a) carcinoma, (b) a sarcoma, or (c) a leukemia (claim 50).

Claim 34 is drawn to distinct species of the claimed invention, wherein the cancer is (a) carcinoma, (b) a sarcoma, or (c) a leukemia (claim 50).

Claims 31 and 34 are drawn to distinct species of the claimed invention, wherein the nucleic acid molecule of claim 31 or 34 has a nucleotide sequence that is at least (a) 70%, (b) 75%, (c) 80%, (d) 85%, (e) 90%, (f) 95%, or (g) 99% identical to the reference sequence (claim 38).

Claim 42 is drawn to distinct species of the claimed invention, wherein the tumor cell is (a) carcinoma cell, (b) a melanoma cell, or (c) a leukemia cell (claim 43).

Claim 43 is drawn to distinct species of the claimed invention, wherein the carcinoma cell is one of the carcinoma cells of the group listed in claim 44.

Claim 47 is drawn to distinct species of the claimed invention, wherein the cancer is (a) carcinoma, (b) a sarcoma, or (c) a leukemia (claim 50).

Claim 50 is drawn to distinct species of the claimed invention, wherein the carcinoma is one of the carcinomas of the group listed in claim 51.

Claim 50 is drawn to distinct species of the claimed invention, wherein the sarcoma is one of the sarcomas of the group listed in claim 52.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each species relates to products that are biologically and chemically distinct molecules or to materially different methods.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to written restrictions.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Stephen L. Rawlings, Ph.D.

Examiner

Art Unit 1642

slr

October 1, 2001



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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